PHARMACISTS' BULLETIN

NOVA SCOTIA SENIORS' PHARMACARE PROGRAM
PHARMACARE
NOVA SCOTIA DEPARTMENT OF COMMUNITY SERVICES

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NOVEMBER BULLETIN

Compounded Products Insured

The following is a complete list of compounded products which are fully insured under the Pharmacare Programs. Each compound has been assigned a corresponding DIN which is to be used when submitting a compound claim. Please do not use the DIN of the main ingredient for compounds.

Product	DIN
Anthralin Soft 0.05% Paste	00902063
Anthralin Soft 0.1% Paste	00900907
Anthralin Soft 0.2% Paste	00900915
Anthralin Weak 0.2% Oint	00901105
Anthralin 0.4% Oint	00901113
Hydrocortisone Pdr 1% - 2.5% in Clotrimazole Cr	00999474
Hydrocortisone 0.5% in Soft Petrolatum	00903175
Hydrocortisone 1% in Soft Petrolatum	00903183
LCD (Coal Tar) Preparations	00358494
LCD 20% USP	00358495
Salicylic Acid Oint	00900788
Tar Pomade	00901121

A Reminder When Changing Brands . . . .

When an exception status drug has been approved for a patient and where there may be a number of interchangeable generic products every effort is made at the Pharmacare office to approve the generic brands that are used by the dispensing pharmacy. However, if your pharmacy inventory changes to a different generic brand of an approved exception status product and you begin dispensing a generic that has not already been approved for the patient, the claim will be rejected. If this situation occurs, please contact the Pharmacare office (496-7001 or 1-800-305-5026) to have the alternate generic brand included in the exception status coverage for the patient.

Hydrocortisone Preparations

Due to a shortage of commercial hydrocortisone preparations, manually compounded hydrocortisone preparations had been approved for reimbursement only until the commercial preparations become available. As the cream base hydrocortisone preparations are now available on the market, *effective immediately* the following manually compounded preparations will no longer be insured under the Pharmacare Programs.

Product	DIN
Hydrocortisone 0.5% in Dermabase	00903124
Hydrocortisone 0.5% in Glaxal Base	00903159
Hydrocortisone 1% in Dermabase	00903132
Hydrocortisone 1% in Glaxal Base	00903167

Please Note: The manually compounded ointment base preparations (soft petrolatum) will continue to be insured until further notice.

Nurse Practitioners Prescribing List

The College of Registered Nurses of Nova Scotia has recently expanded the range of medications which nurse practitioners can prescribe. Subsequently, the Nova Scotia Pharmacare Programs is in the process of updating the specific list of drugs which can be reimbursed under the Pharmacare Programs when prescribed by a nurse practitioner. Until this process is complete, these drugs will not be re-imbursed as a benefit when prescribed by a nurse practitioner.

INCLUDED WITH THIS BULLETIN:

- **New Products List**, *eff. December 1, 2005*
- **Calcium & Vitamin D in the Elderly - To Supplement or Not?**

NEW PRODUCTS

The following products are "New Listings to the Nova Scotia Formulary" ***effective December 1, 2005***. The benefit status of each product within the Nova Scotia Pharmacare Programs is indicated.

DIN	PRODUCT	MFR	BENEFIT STATUS
02259052	Amevive 15mg/0.5mL Pdr for Inj	BIG	not insured
02258528	Edecrin 25mg Tab	MSD	SF
02248625	Fosamax 70mg/75mL Oral Sol	MSD	not insured
02245689	Lantus 100iu/mL Vial	SAN	not insured
02182750	Methotrexate 10mg Tab	DBU	SFC
02223740	Norprolac 0.025mg Tab	FEI	not insured
02223759	Norprolac 0.05mg Tab	FEI	not insured
02223767	Norprolac 0.075mg Tab	FEI	not insured
02223775	Norprolac 0.15mg Tab	FEI	not insured
02254735	Oxytrol Patch (3.9mg/day 36mg/patch)	PAL	not insured
02266717	Reminyl ER 8mg Cap	JAN	E
02266725	Reminyl ER 16mg Cap	JAN	E
02266733	Reminyl ER 24mg Cap	JAN	E
02255707	Risperdal Consta 25mg/2mL Inj	JAN	E
02255723	Risperdal Consta 37.5mg/2mL Inj	JAN	E
02255758	Risperdal Consta 50mg/2mL Inj	JAN	E
02247228	Stieprox 1.5% Shampoo	STI	not insured
02262800	Strattera 10mg Cap	LIL	not insured
02262819	Strattera 18mg Cap	LIL	not insured
02262827	Strattera 25mg Cap	LIL	not insured
02262835	Strattera 40mg Cap	LIL	not insured
02262843	Strattera 60mg Cap	LIL	not insured
02248761	Viracept 625mg Tab	PFI	not insured

CRITERIA FOR NEW BENEFITS WITH EXCEPTION STATUS

Risperidone (Risperdal Consta)

- for patients with a history of non-adherence *and*
- inadequate control or significant side-effects from two or more oral antipsychotic medications *and*
- inadequate control or significant side-effects from at least **one** typical depot antipsychotic agent

Galantamine (Reminyl ER)

The new extended release formulation has been added following the same criteria already established for Cholinesterase Inhibitors.

ADDITION TO EXCEPTION CRITERIA FOR VALGANCICLOVIR

The criteria for valganciclovir (Valcyte®) has been expanded to include the following criteria:

- for the prevention of CMV disease post kidney, heart, liver or kidney-pancreas transplantation in patients at high-risk (D + / R-) (i.e., donor positive/recipient negative)
- coverage will be for a maxiumum of 90 days

Calcium and Vitamin D in the Elderly
To Supplement or Not?

Diane Theriault, MD, FRCPC, Rheumatologist
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The RECORD (Randomised Evaluation of Calcium Or vitamin D) trial, recently published in The Lancet, has resulted in questions about the previously believed benefits of supplemental treatment with calcium and vitamin D in the elderly population.

Before discussing the RECORD trial in detail, it is helpful to state a few definitions and some facts from previous calcium and vitamin D trials.

Definitions

- Primary prevention: preventing development of osteoporosis, keeping BMD above -2.5
- Secondary prevention: preventing first fracture in patients with osteoporosis (BMD already less than or equal to -2.5)
- Tertiary prevention: preventing a recurrent fracture

Previous trials

- The landmark primary prevention trial by *Chapuy et al* found that daily treatment with calcium and vitamin D significantly reduced the risk of hip and non-vertebral fractures compared with calcium alone in elderly women living in a nursing home. It is likely that trial patients (n = 3270) were all vitamin D deficient based on the low levels reported for the small subgroup of patients (n = 142) that were assessed at baseline, serum 25-hydroxyvitamin D levels were 33 nmol/L. This trial can only be considered a primary prevention study since BMD or prior fracture incidence was not reported for the majority of patients.
- A subsequent primary prevention study by *Dawson-Hughes et al* found daily treatment with calcium and vitamin D reduced bone loss and fracture risk compared with calcium alone in ambulatory men and women in the community setting. The study, however, was not powered for fracture reduction. Baseline vitamin D levels were measured for all patients and were 82.5 nmol/L of 25-hydroxyvitamin D. This trial was considered a primary prevention trial because patients were picked based on age only, BMD measurements or previous fractures were not considered at inclusion.
- A primary prevention trial by *Trivedi et al*, found 100 000 IU of vitamin D given alone every 4 months for 5 years significantly reduced fractures in community dwelling patients compared with placebo. Serum 25-hydroxyvitamin D was not assessed at baseline but was measured after 4 years in a subgroup and was 53.3 nmol/L in the placebo group.
- A large primary prevention study of 9,440 community-dwelling patients who received a large once yearly vitamin D injection (300,000IU) failed to show any protective effect on fractures. As with other trials, vitamin D status was only assessed in a small subgroup of patients.
- Several trials show small, but consistent fall reduction benefit of vitamin D (usually at doses of 800 IU or higher).

It is not clear from the above studies:

- whether vitamin D needs to be combined with calcium. It is difficult to determine which agent is doing more good at the bone.
- what effect vitamin D with or without calcium has in the secondary[b] or tertiary[c] prevention of osteoporotic fractures.

The RECORD trial attempted to address these questions.

RECORD trial

The RECORD trial was a large randomised **tertiary[c] prevention** trial involving 5,292 patients, 70 years of age or older with previous fragility fracture. Eighty five percent of the population was women. Patients were randomised to one of four groups:

- calcium 1000 mg daily
- vitamin D3 800 IU daily
- calcium 1000 mg daily plus vitamin D3 800 IU daily
- placebo.

Patients were followed up for between 24 and 62 months. The primary outcome was new low-energy fractures. After 24 months there were no significant differences in fracture rates between the four groups.

The authors of the RECORD trial concluded that "the findings do not support routine oral supplementation with calcium and vitamin D3, either alone or in combination, for the prevention of further fractures in previously mobile elderly people". This interpretation is limited by several factors:

- Patients with severe osteoporosis (existing fragility fracture) require treatment with an antiresorptive agent along with calcium and vitamin D, they are not treated with calcium and vitamin D alone. The intent of the factorial design of the RECORD trial was to determine the relative contributions of calcium versus vitamin D on fractures in patients with existing fragility fractures (tertiary prevention). However, since randomised control trial evidence shows that secondary and tertiary prevention of fractures is only achieved with antiresorptive treatment in combination with calcium and vitamin D, the results contribute little to current clinical practice. The more clinically relevant question is, in patients with osteoporosis (BMD ≤ -2.5 and/or fragility fracture), is there any benefit to adding calcium and vitamin D? Unfortunately, the RECORD trial does not answer this question. The rate of placebo patients who got bisphosphonates was very low in the RECORD trial with 3.5% receiving treatment at 1 year and 4.5% at 2 years.
- Compliance with study medication was poor. It declined to 63% after two years and may even be argued to be as low as 45% when non-responders to the questionnaire about compliance were included.
- The study suffers from the same limitation as the previous trials in that measurement of serum 25-hydroxyvitamin D levels was only done in a small sample of the study population, just 60 people (1.1%). The vitamin D status of the majority of the population at baseline is not known. It has been speculated that because the population was younger and more ambulatory, relative to the other trials, that they were less likely to have vitamin D deficiency. However, baseline results of the small sample group indicate otherwise. The baseline mean concentration of 25-hydroxyvitamin D was only 37.94 nmol/L. After one year of supplementation, those allocated to 800 IU of vitamin D3 treatment had increased serum levels of 62 nmol/L. It is generally accepted that the desirable serum 25-hydroxyvitamin D levels should be 80 nmol/L or higher to avoid secondary hyperparathyroidism with PTH elevations. It is possible that the 800 IU dose of vitamin D3 was not sufficient to raise their 25-hydroxyvitamin D levels above 80 nmol/L.

Conclusion

What can be concluded from the current Calcium and vitamin D trial evidence?

- Overall, it appears that vitamin D given in combination with calcium reduces fracture risk in people deficient in vitamin D.
- In community dwelling patients that are not vitamin D deficient, the benefits of vitamin D and calcium are less clear.
- The effects of vitamin D with or without calcium on falls need clarifying.

More studies are needed in older patients whose baseline vitamin D status has been clearly established to unequivocally determine the benefit of vitamin D with and without calcium on both falls and fractures. Until that time, current evidence supports the need for adequate vitamin D and calcium intake for the primary[a], secondary[b], and tertiary[c] prevention of fractures. The RECORD trial did show disappointing results for tertiary prevention[c] when vitamin D and calcium were used alone. However, this patient population as well as those with a BMD less than -2.5 without fracture, require an antiresorptive in combination with vitamin D and calcium supplements since this is the only treatment regimen that has been shown to reduce fractures in these patients. The fracture reduction benefit of antiresorptives without calcium and vitamin D supplements in patients with osteoporosis (BMD ≤ -2.5 and/or fragility fracture) is not known.

People living in long term care are at greatest risk of vitamin D deficiency. It has been suggested that the problem of diminished vitamin D nutrition, that is at least partly due to less sunlight exposure, should be treated with a vitamin D supplement of at least 1000 IU daily all year around. Some physicians supplement their elderly patients with 2000 IU daily to achieve serum 25 (OH)D levels above 80 nmol/L.

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